DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 10, 2015

CAS Medical Systems, Inc.
Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Rd.
Branford, Connecticut 06405

Re: K143675
Trade/Device Name: Fore-Sight Elite Absolute Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: March 18, 2015
Received: March 19, 2015

Dear Ron Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

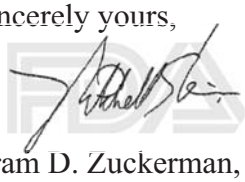
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address \http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number: K143675

Device Name: FORE-SIGHT ELITE® Absolute Tissue Oximeter.

Indications for Use: The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

- When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with Medium Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on pediatric subjects ≥3 kg.
- When used with Small Sensors, the FORE-SIGHT ELITE Oximeter is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5 kg.

Prescription Use ✔ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

6. 510(k) Summary

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
K143675

Submitter: CAS Medical Systems, Inc.

Address: 44 East Industrial Rd. Branford CT. 06405 USA

Contact: Ron Jeffrey – Director, Regulatory Affairs
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Prepared: December 22, 2014

Trade Name: FORE-SIGHT ELITE® Absolute Tissue Oximeter

Common Name: FORE-SIGHT Oximeter

Classification Name: Oximeter, Tissue Saturation (870.2700) (MUD)

Predicate Device(s):

- FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor (K133879)
- FORE-SIGHT Absolute Tissue Oximeter Monitor (K112820)
- Nonin Model 7600 Regional Oximeter Equanox (K113215)

DESCRIPTION

The FORE-SIGHT ELITE Absolute Tissue Oximeter measures hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation saturation in the tissue (StO2).

The Oximeter consists of a monitor unit, preamplifier assembly, and Small, Medium and Large Sensors. The Sensors use multiple wavelengths in the range of 660 to 900 nm to precisely measure light absorption in tissue. Sensors are sized to provide targeted penetration depths appropriate for the tissue and patient populations of interest. The monitor unit controls the measurement sequence, generating the sensor LED currents and processing the detected light signals after amplification by the dual-channel preamplifier assembly. The FORE-SIGHT algorithm determines the StO2 values for the tissue under the sensor from the light absorption values and measured patient characteristics. The monitor unit provides simultaneous measurements on up to four Sensors with both numeric and real-time graphical display formats.

The monitor unit is a mains-powered device with a field-replaceable battery backup module. A touchscreen user interface allows configuration of the Oximeter including audible, on-screen, and dedicated visual alarm indicators. The monitor display can be replicated for simultaneous remote viewing through an auxiliary VGA video output. Measurement data can be exported through various interfaces such as USB and RS-232.

FORE-SIGHT Oximeter Monitor Intended Use

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg. When used with Medium Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on pediatric subjects ≥3 kg. When used with Small Sensors, the FORE-SIGHT ELITE Oximeter is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

FORE-SIGHT Monitor Technology Compared to Predicate Devices

The FORE-SIGHT ELITE Absolute Tissue Oximeter compares substantially to the cited predicate devices in that they use fundamentally the same optical operating principle, called multi-distance diffuse reflectance spectroscopy. All cited monitors use light to examine a cross-section tissue microvasculature (a mixed bed of arterioles, capillaries and venules). The FORE-SIGHT ELITE Monitor and predicate devices analyze the light that is returned after having passed through tissues. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states. All cited monitors calculate oxygen saturation which reflects the percentage of oxygenated hemoglobin in the sampled tissue.

The following table compares design, materials, energy and others characteristics.

Characteristic	K143675 (this Submission)	CASMED ELITE K133879	CASMED K112820	NONIN K113215	How They Compare
FDA Classification	Class II, 870.2700, MUD	Class II, 870.2700, MUD	Class II, 870.2700, MUD	Class II, 870.2700, MUD	Same
Purpose	Detect changing levels in cerebral or somatic oxygenated hemoglobin in sampled tissue	Detect changing levels in cerebral or somatic oxygenated hemoglobin in sampled tissue	Detect changing levels in cerebral or somatic oxygenated hemoglobin in sampled tissue	Detect changing levels in cerebral or somatic oxygenated hemoglobin in sampled tissue	Same
Indicated For	Adults and Pediatric subjects depending on sensor size	Adult and Transitional adolescents	Adults and Pediatric subjects depending on sensor size	Adults and Pediatric subjects	Same as CASMED predicate
Parameters Monitored	Single	Single	Single	Single	Same
Technology	Near-infrared Spectroscopy (NIRS)	Near-infrared Spectroscopy (NIRS)	Near-infrared Spectroscopy (NIRS)	Near-infrared Spectroscopy (NIRS)	Same
Monitoring Channels	4 - Channels	4 - Channels	2 - Channels	4 - Channels	Same as CASMED predicate
System Components	Monitor, Preamp, Sensor	Monitor, Preamp, Sensor	Monitor, Preamp, Sensor	Monitor, Preamp, Sensor	Same
Power Requirements	100 to 240 VAC 50/60 Hz and Lead Acid Battery	100 to 240 VAC 50/60 Hz and Lead Acid Battery	110 to 240 VAC 50/60 Hz and Lead Acid Battery	100 to 240 VAC 50/60 Hz and Li-ion Battery	Same as CASMED predicate
Sensor Size(s)	(4) Large, Medium, Small and Small Non-adhesive	(1) Large	(4) Large, Medium, Small and Small Non-adhesive	(2) sizes, one with adhesive, one without	Same as CASMED predicate
Sensor Light Source	LED	LED	Laser Photo Diode	LED	Same as most predicates
Operating Modes	Continuous	Continuous	Continuous	Continuous	Same
Patient Contact Material	Medical Adhesive and Orthopedic foam/fabric composition (small non-adhesive)	Medical Adhesive	Medical Adhesive and biocompatible fabric (small non-adhesive)	Unknown	Similar to CASMED predicate

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The FORE-SIGHT ELITE Absolute tissue Oximeter has successfully undergone extensive performance, (safety, electromagnetic, and system testing) to ensure it has been found to be substantially equivalent to the predicate devices. Evaluation for the safety of materials is assured by biological testing under the standard ISO10993-1. All testing is a product of the risk management process.

Test standards met:

Category	Testing Summary
Electrical Safety and Usability	• ANSI/AAMI ES60601-1: (2005) • IEC 60601-1-8: (2006) • IEC 60601-1-6: (2010) • IEC 62366: (2007)
Electromagnetic Testing	• IEC 60601-1-2: (2007)
System Functional and Performance Testing	The FORE-SIGHT ELITE Oximeter was designed and developed in accordance with CASMED development processes and was verified and validated. Test results demonstrated that the oximeter complies with its predetermined specification.

Clinical Testing to Show Substantial Equivalence

The FORE-SIGHT ELITE Absolute Tissue Oximeter was clinically validated for cerebral and non-cerebral body locations on a demographically diverse population of 136 subjects at multiple institutions with ages ranging from 1 day to 17 years old including very low birth weight and premature neonates. Measurements of the tissue oxygenation were calibrated against a weighted co-oximetry reference of arterial and venous blood samples drawn simultaneously from vascular locations appropriate to the tissue of interest (jugular bulb, central venous, umbilical venous) with a 30% arterial and 70% venous contribution. Tissue saturations were obtained in the range of 48-96%. Accuracy was determined as a bias and precision to the weighted co-oximetry reference with values from 0.05 ± 5.06% to 0.03 ± 5.69% depending upon body location. No safety issues or adverse events related to the FORE-SIGHT ELITE Absolute Tissue Oximeter were encountered.

Conclusions Drawn from Clinical and Non-Clinical Testing

Clinical evaluation, safety testing and software validation demonstrate the FORE-SIGHT ELITE Absolute Tissue Oximeter is substantially equivalent to the predicate devices.